

The Role of National Registries in Improving Quality of Care and Outcomes for Cardiovascular Disease

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ABSTRACT: Cardiovascular registries play an integral role in providing real-world data on a number of cardiovascular conditions and allowing measurement of quality metrics across a large cohort of patients. Over the past 35 years, the number of cardiovascular registries has skyrocketed, and their use will only continue to grow as data on novel procedures and devices will need to be collected and analyzed. The American College of Cardiology and Society of Thoracic Surgeons Transcatheter Valve Therapy Registry is just one example of a modern registry that plays a crucial role in collecting data on patients undergoing transcatheter valvular procedures. Through public reporting registries, data can be shared on a hospital and provider level for many quality performance measures. There remains much work to be done on allowing automated data extraction from the electronic medical record directly into registries. No matter how sophisticated and complete a registry is, it can never overcome the problem of treatment selection bias that is inherent in observational data. This review discusses the growth, benefits, and limitations of national registries and their role in developing evidence for best clinical practice, measuring outcomes, providing feedback to clinicians, and improving quality of care.

INTRODUCTION

Over the past 35 years, the number of cardiovascular registries has grown rapidly. Much of the current guidance for registries is based on a statement from a 2015 joint working group of the American College of Cardiology (ACC), American Heart Association (AHA), and Society of Thoracic Surgeons (STS) wherein they sought to define the future of cardiovascular registries and their role in performance measurement. According to this statement, a clinical registry is an observational database focused on a clinical condition, procedure, therapy, or population. In these registries, data are collected systematically for specified scientific, clinical, or policy purposes.¹

The focus of clinical registries is capturing data that reflect real-world clinical practice across a large patient landscape. While the randomized clinical trial is the gold standard for studying medical therapeutics, it does not offer the vast amount of data and generalizability available in a clinical registry. Rather, registries and clinical trials are complementary sources of information. If used appropriately, clinical registries can harness big data to provide insights into patient characteristics, comorbid conditions, patterns of care, quality of care, safety, underlying trends, clinical outcomes, and comparative effectiveness.² As Dr. Lukas Kappenberger said in 2005, "Science tells us what we can do; guidelines what we should do; and registries what we are actually doing."^{3,4}

HISTORY

Professional societies gave clinical registries their start in the 1980s. Since then, these registries have grown immensely

and now involve stakeholders ranging from patients and physicians to health systems and professional societies (Table 1). Some of today's best-known societies are the STS National Database, ACC National Cardiovascular Data Registry, and AHA Get With The Guidelines.⁵ Prospective registries first became popular as components of randomized trials. One of the earliest examples is the Coronary Artery Surgery Study (CASS), a randomized trial of bypass surgery versus medical therapy performed in the 1980s.⁶ Patients in the CASS registry were screened but not randomized. The registry component demonstrated that the findings from the randomized trial were generalizable and provided additional insights into subgroups not treated in the trial. Registries were then expanded to local databases developed at large academic institutions, with the Duke database being one of the earliest.⁷ This was followed by regional and national registries, such as the National Heart Lung and Blood Institute Percutaneous Transluminal Coronary Angioplasty Registry in 1980.⁸ The first registry to measure quality of care in a large population of patients with acute myocardial infarction (MI) was the Cooperative Cardiovascular Project, started in the early 1990s by the Health Care Finance Administration, now known as the Centers for Medicare and Medicaid Services (CMS).⁹

CURRENT REGISTRIES

Registries can be classified by a demographic group or by the defining characteristics of the patients enrolled, such as a specific procedure (eg, CathPCI Registry), therapy, or disease (eg, Diabetes Collaborative Registry).^{10,11} There are also local and state registries that monitor outcomes.¹²

| REGISTRY | GOVERNANCE | DESCRIPTION | SIZE/RECORDS | SUB-REGISTRIES |
|--|--|---|---|--|
| National Cardiovascular Data Registry (NCDR) | American College of Cardiology | Composed of 10 registries: 8 inpatient/procedure based and 2 outpatient based | > 2,400 hospitals and 8,500 providers with > 60 million patient records | Examples include CathPCI, LAAO, Afib Ablation, and the Diabetes Collaborative Registry |
| Society of Thoracic Surgeons (STS) National Database | Society of Thoracic Surgeons | Clinical outcomes for patients who undergo cardiothoracic surgery | Includes > 90% of adult cardiac surgical centers and > 6.9 million surgical cases | Examples include Adult Cardiac Surgery Database, General Thoracic Surgery Database |
| Transcatheter Valve Therapy (TVT) | Society of Thoracic Surgeons/ American College of Cardiology | Focused on patients who undergo transcatheter valve replacement and repair procedures such as TAVR | > 650 sites reporting | n/a |
| Get With The Guidelines (GWTG) | American Heart Association | Reports patient outcomes on a number of cardiovascular conditions, such as stroke, heart failure, and atrial fibrillation | > 2,000 hospitals | GWTG Stroke, GWTG Heart Failure, GWTG COVID-19 CVD Registry |
| Hospital Compare | Center for Medicare and Medicaid Services | Public reporting comparing hospitals based on overall star rating and certain quality measures | > 4,000 Medicare-certified hospitals | n/a |
| Hypertrophic Cardiomyopathy Registry | University of Virginia/ University of Oxford | Identifies markers that predict development of complications in patients with HCM | 44 active sites; 2,750 patients enrolled | n/a |

Table 1.

Description of representative cardiovascular disease registries. LAAO: Left Atrial Appendage Occlusion Registry; PCI: percutaneous coronary intervention; Afib: atrial fibrillation; TAVR: transcatheter aortic valve replacement; HCM: hypertrophic cardiomyopathy; CVD: cardiovascular disease

In addition to simply aggregating real-world data, registries provide quality measurement, feedback to physicians for quality improvement, or clinical research. The governance of registries varies according to the purpose and entity that operates them, whether it be a professional society (such as ACC, AHA, or STS), researcher, research consortia, nonprofit organization, government agency (eg, National Institutes of Health), or industry. Registries that are operated by researchers are typically governed by the founding investigators, whereas industry-funded registries are controlled by the sponsoring

company. Specialty society registries such as the STS/ACC Transcatheter Valve Therapy Registry are governed by society members.¹³

In 1987, the ACC established the National Cardiovascular Data Registry (NCDR) with the initial goal of defining clinical characteristics and outcomes of patients undergoing cardiac catheterization and coronary intervention.^{14,15} It has grown rapidly and now includes more than 1,500 US hospitals and 2 million patient records. Of its 10 registries, 8 are inpatient/

procedure based and 2 outpatient.¹¹ NCDR now has more than 60 million records, making it a useful source of big data in cardiovascular disease outcomes.¹⁶

The STS National Database is one of the largest and most successful national registries.^{17,18} It was established in 1989 and now has more than 6.9 million surgical cases and participation from more than 90% of all adult cardiac surgical centers.¹⁹ The newest STS registry is the STS/ACC Transcatheter Valve Therapy (TVT) Registry, which monitors patient safety and real-world outcomes related to transcatheter valve replacement and repair procedures.²⁰ As of October 2019, there were over 650 sites reporting transcatheter aortic valve replacement data to the TVT registry.⁴

BENEFITS OF CLINICAL REGISTRIES AND BIG DATA

To be successful, clinical registries must be able to collect large amounts of data (ie, big data) in a structured and systematic manner.²¹ Data are captured using standardized, granular, and consistent data definitions and standards. Some registries are now able to extract structured data directly from electronic medical records (EMRs).²² Some institutions have been able to integrate data collection for registries into their clinical workflow, limiting expensive and time-consuming data abstraction. This is best approached by collecting structured data for clinical reporting.²³ For instance, laboratory data are standardized by LOINC and pharmaceutical data standardized by RxNorm.^{24,25} Other standardized data are based on Health Level 7 (HL7) standards, a set of international standards and guidelines used to transfer and share data between various health care systems.²⁶

Data entered into registries that cannot be automatically transmitted or imported from EMRs require specialized data abstractors. Historically, data have been extracted from EMRs by nurse abstractors, data managers, or study coordinators who are trained to abstract the information according to specific definitions.¹¹ The information can then be entered into the registry via case report forms. This results in highly valid and reliable information in the registries. However, registries must have processes in place to ensure data quality. The STS National Database, AHA Get With The Guidelines Registry, and NCDR have ongoing abstractor training and a robust data auditing process.²⁷ The STS audits roughly 10% of the participant sites annually; for instance, in 2013 they audited almost 100,000 individual data elements with an overall accuracy rate of 96.6%.¹⁸ This is in contrast to EMR data, which address quality through post hoc evaluation rather than auditing. EMR data, such as diagnosis and treatment codes, are used primarily for billing and insurance purposes.

Clinical registries play a critical role in the cycle of developing evidence for best clinical practice, measuring outcomes, providing feedback to clinicians, and improving quality of care. Because they span domains from clinical care to research to quality improvement, they sometimes present ethical and regulatory challenges. Recent efforts have examined the possibility of using clinical registries as a platform to conduct pragmatic clinical trials. For instance, the TASTE (Thrombus Aspiration in Myocardial Infarction) trial is part of the SWEDEHEART Registry, and the SAFE-PCI (Study of Access Site for Enhancement of Percutaneous Coronary Intervention) for Women trial is embedded in the NCDR.¹⁶ In the TASTE trial, 7,244 patients with ST-segment elevation MI were randomized to thrombus aspiration with PCI versus PCI alone. Thrombus aspiration was not shown to reduce the incidence of the composite end point of death, recurrent MI, and stent thrombosis.²⁸ In SAFE-PCI for Women, 1,718 women undergoing diagnostic cardiac catheterization or PCI were randomized to radial versus femoral arterial access. There was no significant difference in bleeding or vascular complications between the two different access sites.²⁹ Although these trials and their results are relatively unremarkable, they demonstrate proof of concept for conducting a randomized clinical trial embedded in a clinical registry. Such an approach is potentially much less expensive than performing a clinical trial and may increase generalizability.

PUBLIC REPORTING

Through public reporting, clinical registries can provide feedback to clinicians about their own outcomes, which can then be benchmarked against regional and national data with the ultimate goal of improving care. The modern era of public reporting started around 1989 in New York, where the New York State Department of Health started collecting surgeon-specific mortality data after coronary artery bypass grafting (CABG).^{12,30} Although initially not meant for public disclosure, the data were published in 1991 after the publication *Newsday* filed a Freedom of Information Act petition.³¹ Now CABG mortality rates for hundreds of hospitals are publicly disclosed through the STS National Database.³² Unlike the STS registry, the CathPCI registry from the NCDR is not reported publicly and primarily measures data at the hospital level rather than the physician level.³³ CMS publicly discloses Medicare quality metrics, many of which involve cardiovascular conditions such as acute MI and congestive heart failure hospitalizations.³⁴ Since initiation of the CMS Hospital Value-Based Purchasing program, an increasing number of publicly reported quality metrics are affecting hospital reimbursement.³⁵ Clinical registries have been instrumental in creating these quality metrics, and they have been endorsed by many professional societies and the National Quality Forum.³⁶

Public reporting has been criticized on a number of grounds. The primary reason for public reporting is to benchmark hospitals and providers, offering data that is, in principle, objective and allows patients to make informed choices.^{34,37} However, there are limitations to data quality, and methods used to compare hospitals may not adequately correct for disease severity.³⁸ To reduce the risk of being penalized, hospitals and providers may avoid offering care to the most critically ill or may try to circumvent hospital readmissions for conditions such as heart failure, which can lead to increased mortality.³⁹ There are also statistical limitations because the large number of institutions being compared relative to the small number of procedures and complications within individual institutions makes statistical comparisons unreliable.³⁷ Finally, there are differences in the type of data reported. For instance, CMS and commercial groups rely on administrative data for public reporting, while STS uses their national database.

LIMITATIONS

It is equally important to understand the shortcomings of clinical registries. With the growing number of registries, there is an increased administrative burden on participating centers to manually extract and validate data before reporting it to the registry. At large community hospitals and academic centers, there are often multiple full-time personnel who perform this work for the multicenter societal registries. However, since centers are not compensated for participating in the registry, they must bear this cost.⁴⁰ Health care systems may not value participation in these registries, preferring to evaluate outcomes from administrative data. This is a threat to the long-term sustainability of societal registries.

There is significant redundancy in collecting similar data for multiple registries, as each uses slightly to significantly different definitions for variables. For instance, the definitions of diabetes mellitus and hyperlipidemia differ in the implantable cardioverter defibrillator, PCI, and STS registries.⁴⁰ Unfortunately, one cannot rely purely on EMRs to know if certain criteria were met for a specific definition for a registry. Resolving this problem within EMRs is impractical, as the medical record is neither created nor used with the aim of creating data sets for scientific research but rather to document and coordinate clinical care and perform administrative functions.¹⁶ The lack of standardized definitions for certain conditions across all registries limits EMRs as a way to directly upload registry data. Efforts by the ACC, AHA, and other organizations to develop data standards are ongoing.⁴¹ The goal is interoperability across platforms that collect clinical data.^{42,43} However, this is a monumentally difficult task with no resolution in sight.

Another limitation occurs when patients are transferred from an outside hospital to a tertiary care center. Typically, they arrive

with outside hospital records, but primary data is initially limited in the EMR. This requires additional time from the nurse or data abstractor to request outside records and obtain the correct information to complete registry forms. While it may sound trivial, this becomes difficult in a practical sense due to the sensitive nature of protected health information and can lead to significant omissions in data required for the registry.⁴⁰

Further complicating matters, the granular data collected for each patient in the registry may amount to hundreds of data points, and it is unclear if all these data are useful. Typically, much of the data are related to the patient's baseline conditions, previous treatments, and outcomes. For instance, CMS requires reporting of only 12 cardiovascular performance measures, some of which include 30-day mortality for acute MI and heart failure hospitalization, aspirin and beta blocker use for acute MI, angiotensin-converting enzyme use for heart failure with reduced ejection fraction, PCI for an acute MI within 120 minutes, and smoking cessation counseling.⁴⁴ However, the registry case report form will detail all the underlying cardiovascular risk factors and current treatments. While all this data may be useful to clarify the characteristics of the patients included in the registry, how much of that will be helpful in defining better quality? How much of it will inform research?

Although there is hope, and previous examples have shown proof of concept of an embedded clinical trial in a registry, it is impossible to overcome treatment selection bias in observational studies.⁴⁵ Treatment selection bias can occur when the therapeutic selection is influenced by certain patient characteristics such as severity of illness and comorbidities. This can lead to confounding variables that may skew outcomes. If not accounted for, confounders will bias the results of observational studies and lead to false conclusions. Statistical methods can be used to reduce bias in confounding variables, but not all confounders are known a priori. Various statistical approaches have been used to reduce treatment selection bias, including multivariate analysis and propensity scores.⁴⁶ A regression model can include the treatment as a covariate along with measured confounders. However, all methods used to overcome treatment selection bias are limited, as they only can account for measured variables and not unmeasured confounders. In addition, while registries are repositories for large amounts of data, the infrastructure is quite different from that of randomized clinical trials, and registries are not oriented to address a specific question as is an independent randomized clinical trial.

FUTURE DIRECTIONS

In many cases, registry reporting is now required to assess performance measures and quality of care. To improve

the usefulness of registries, we must ensure that the data is accurate and easily integrated directly from the EMR. Professional societies in charge of registries must develop standardized definitions of conditions and outcomes that span across all registries. Registries must strike the fine balance between collecting enough information on baseline characteristics and clinical outcomes to adequately describe included patients without wasting resources on unnecessary data. Registry data must be a part of the cycle of quality, which includes clinical evidence, guidelines, performance measures, and outcomes.⁴⁷

CONCLUSION

The expansion of cardiovascular registries has provided valuable information on real-world clinical practice across the spectrum of cardiovascular diseases and procedures. Although registries are useful in providing large databases of generalizable data that can be used to set benchmarks and improve quality and safety, their limitations in data collection and data analysis must be understood in order to prevent drawing incorrect conclusions. Looking forward, registry definitions and data collection should be standardized and streamlined to optimize their potential as tools to improve quality of care.

KEY POINTS

- Clinical registries are large databases of observational data collected systematically to reflect real-world clinical practices and outcomes across large patient populations.
- Registries may be classified by procedure, therapy, disease, or demographic group and may be governed by professional societies, researchers, research consortia, nonprofit organizations, government agencies, or industry.
- Registries can provide more generalizable information than that offered by clinical trials. Through public reporting, registries offer valuable insights into patient characteristics, comorbid conditions, patterns of care, quality and safety, clinical outcomes, and comparative effectiveness that can be used to set benchmarks and quality metrics and improve quality of care.
- The usefulness of registries is limited by inconsistent definitions and data standards, barriers to extracting data from electronic health records, practical burdens on participating centers, excessive data collection, and the inherent treatment selection bias from observational studies.

Conflict of Interest Disclosure:

The author has completed and submitted the *Methodist DeBakey Cardiovascular Journal* Conflict of Interest Statement and none were reported.

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cardiovascular registries, outcomes, quality care, National Cardiovascular Data Registry, medical database, STS National Database, electronic health record

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